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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,858	10/06/2000	Peter Beetham	PM49317/272063	9880
23557	7590	03/16/2005	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/680,858

Applicant(s)

BEETHAM ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/6/2004 & 1/10/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24 and 28-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **STATUS OF THE APPLICATION**

1. This Office action is in response to the Amendment and Remarks filed 6 December 2004, and the correction to the amended claim under 37 CFR 1.121(c) filed 10 January 2005.
2. The rejections under 35 USC 112, second paragraph, are withdrawn in view of Applicant's amendments to the claims.
3. The rejection of claims 30-32 and 36-38 under 35 U.S.C. § 102(a) as being anticipated by Hawkes *et al* is withdrawn in view of Applicant's amendments to the claims.
4. The provisional rejection of claims 30-38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent Application 09/685,403 is withdrawn in view of Applicant arguments.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

6. Claims 24 and 28-38 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 6 August 20034.

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Applicant's arguments filed 6 December 2004 have been fully considered but they are not persuasive.

Applicant argues that the nature of the present invention and the underlying art is such that the only way to obtain a meaningful generic claim is to describe the composition in the basic unit of structure that is well art recognized and that Applicants have discovered that a gene in a microspore can be altered by introducing a mixed duplex oligonucleotide (MDON) into the microspore as taught in the Specification. Applicant further argues that the present claims primarily describe function and lack structure because there is nothing functional about the term MDON it is structure (page 4, 4<sup>th</sup> paragraph of the Remarks). These arguments are not found to be persuasive for the reasons given in the previous Office action. The argument directed to the Kmiec '350 and '181 patents is irrelevant to the instant rejection because each application is examined on its own merits. The invention(s) of claims 30-36 are directed to a product by process wherein the process of making does not adequately describe the product made and hence lacks adequate written description as broadly claimed. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

7. Claims 24 and 28-38 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject

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matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 6 August 2003<sup>4</sup>. Applicant's arguments filed 6 December 2004 have been fully considered but they are not persuasive.

Applicant argues that gene repair, in and of itself, was known in the art at the time of the present priority date and that Applicant is generically claiming their invention in manner that is not gene specific. Applicant argues that the fact that unintended gene mutations may be a result of the methods taught in the specification does not mean that the present claims are not enabled because the intended mutation can easily be identified using routine genetic engineering analysis. Applicant further argues that the essence of the instant rejection is that the Applicant's process must be 100% effective and that Applicant has adequately described how to make the MDONs and make mutated plants having a desired mutation (page 7, 1<sup>st</sup> paragraph of the Remarks). These arguments are not found to be persuasive for the reasons given in the previous Office action. Making mutations in plant cells, encompassed by microspores, using MDONs was not routine in the art at the time of Applicant's invention. Making said mutations using MDONs in a plant cell were not predictable at the time of Applicant's invention as outlined in the previous Office action. Applicant's guidance in the instant specification is prophetic and does not provide an enabling disclosure for the breadth of the claimed invention (pages 27-30 of the specification).

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 30-38 are rejected under 35 U.S.C. § 102(b) as being anticipated by Swanson *et al* 1989 (Theoretical and Applied Genetics 78:525-530).

Swanson *et al* disclose an isolated mutant *Brassica napus* microspore comprising a genomic mutation that confers imidazolinone tolerance and that is regenerable (see page 526, left column). Hence, Swanson *et al* have previously disclosed all of the claim limitations. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

***Claim Rejections - 35 USC § 103***

10. Claims 24, 28, 29 and 33-36 remain rejected and claims 30-32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kmiec (US Patent 5,731,181, filed 17 June 1996) in view of Fennell *et al* (1992, Plant Cell Reports 11:567-570) and Hawkes *et al* (WO 98/54330, published 3 December 1998, priority date 28 May 1997). This rejection has been modified in view of Applicant's amendments to the claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed

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6 August 2003<sup>4</sup>. Applicant's arguments filed 6 December 2004 have been fully considered but they are not persuasive.

The teachings of Kmiec and Fennell *et al* can be found in a previous Office action.

Hawkes *et al* teaches introducing an MDON into a plant pollen cell to introduce a mutation using a biolistic method (page 12, 1<sup>st</sup> paragraph).

The instant claims would have been obvious to one of ordinary skill in the art because a plant microspore comprising a mixed duplex oligonucleotide would have been obvious by modifying the teachings of Kmiec using the teachings of both Fennell *et al* and Hawks *et al*. Fennell *et al* teach that using microspores has the advantage as useful for producing haploid plants that can be used to produce homozygous diploids (see page 567, right column, end of Introduction). Hawks *et al* teach that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to use a biolistic method to introduce MDONs into a haploid plant cell to introduce a genetic mutation.

Applicant argues that the Fennell *et al* reference teaches that transformation of microspores, which is a techniques know in the art but that Fennell *et al* cannot be used as a secondary reference to combine with Kmiec '181 because of the differences already pointed out by the Applicants. Applicants argue that their experience with employing the teachings of Fennell *et al* to transform microspores with the GFP gene has been disappointing and that attempts to introduce the GFP gene in to canola microspores employing similar methods described by Fennell *et al* for transforming corn

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have been unsuccessful and thus there could be no expectation of success in using the much smaller MDONs to produce a targeted mutation according to the present invention (page 6 of the Remarks). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). To address this issue the Examiner has included the teachings of Hawks *et al* which teaches that one of ordinary skill in the art at the time of Applicant's invention would have been motivated to introduce an MDON into a haploid plant cell, such as a plant microspore or pollen cell, using a biolistic method known in the art.

### ***Double Patenting***

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. § 101.

12. Applicant is advised that should claims 30 and 31 be found allowable, claims 34 and 35 will be objected to under 37 CFR § 1.75 as being a substantial duplicate thereof.



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When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

**Conclusion**

13. This Office action is made non-final because it put forth new rejections not previously presented.

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written over a circular stamp or mark.

David H. Kruse, Ph.D.  
11 March 2005

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16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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